

# Notice of Allowability

Application No.

10/643,349

Examiner

S. Devi, Ph.D.

Applicant(s)

SEID, ROBERT

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's after-final amendment filed 10/11/06.
2. ☒ The allowed claim(s) ~~is/are~~ 32 and 50-55, now renumbered as claims 1 and 2-7 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☒ Other IDS page 1 of 5 09 2004.

## ATTACHMENT TO NOTICE OF ALLOWABILITY

### Applicant's After-Final Amendment

- 1) Acknowledgment is made of Applicant's after-final amendment filed 10/11/06 in response to the final Office Action mailed 07/25/06.

### Examiner's Amendment

- 2) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Ms. Amy Hessler in a telephonic interview on 25 October 2006.

This application has been amended as indicated below:

- (a) Claim 32 has been amended as indicate below:

--Claim 32 (Currently amended). A substantially homogenous sized *Neisseria meningitidis* serogroup B capsular oligosaccharide (MenB OS)/CRM<sub>197</sub> toxoid glycoconjugate produced by a method comprising:

- (a) providing a heterogenous population of MenB OS in which sialic acid residue N-acetyl groups are replaced with saturated N-propionyl groups;
- (b) obtaining a substantially homogenous sized group of MenB OS from the population of step (a) wherein said MenB OS have an average degree of polymerization (Dp) of about 12 to 18;
- (c) covalently attaching a C3-C16 long-chain aliphatic lipid to the nonreducing end of the MenB OS obtained in step (b);
- (d) introducing a reactive group at the reducing end of the MenB OS obtained in step (b) to provide single end-activated MenB OS of said DP; and
- (e) covalently attaching the single end-activated MenB OS obtained in step (d) to a CRM<sub>197</sub> ~~bacterial~~ toxoid carrier molecule to provide the substantially homogenous sized MenB OS/CRM<sub>197</sub> toxoid glycoconjugate.--

### **Status of Claims**

- 3) Claims 31, 43 and 45-47 have been canceled via the amendment filed 10/11/06.  
Claim 31 has been amended via this Examiner's amendment.  
Claims 32 and 50-55 are pending and are under examination.

### **Terminal Disclaimer**

- 4) Acknowledgment is made of Applicant's terminal disclaimer filed 10/11/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent 6,638,513.

### **Rejection(s) Moot**

- 5) The rejection of claims 31, 43 and 45-47 made in paragraph 8 of the Office Action mailed 09/30/04 and paragraph 12 of the Office Action mailed 09/29/05 and maintained in paragraph 12 of the Office Action mailed 03/26/05 and paragraph 6 of the Office Action mailed 07/25/06 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of the U.S. Patent 6,638,513, is moot in light of Applicants' cancellation of the claims.
- 6) The rejection of claim 31 and those dependent therefrom made in paragraph 23 of the Office Action mailed 03/26/05 and maintained in paragraph 13 of the Office Action mailed 09/25/05 and paragraph 7 of the Office Action mailed 07/25/06 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claims.

### **Rejection(s) Withdrawn**

- 7) The rejection of claims 32 and 50-55 made in paragraph 8 of the Office Action mailed 09/30/04 and paragraph 12 of the Office Action mailed 09/29/05 and maintained in paragraph 12 of the Office Action mailed 03/26/05 and paragraph 6 of the Office Action mailed 07/25/06 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of the U.S. Patent 6,638,513, is withdrawn in light of Applicant's terminal disclaimer filed 10/11/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of US Patent 6,638,513.

### Remarks

- 8) Claims 32 and 50-55, now renumbered as claims 1 and 2-7 respectively, have been allowed.
- 9) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number (571) 273-8300, which receives facsimile transmissions 24 hours a day and 7 days a week.
- 10) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- 11) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Acting Supervisor, Albert Navarro, can be reached on (571) 272-0861.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

October, 2006

  
S. DEVI, PH.D.  
PRIMARY EXAMINER